

United States Country Comments
Guidelines for the Use of Irradiation as a Phytosanitary Measure
October 2002

General: The United States generally accepts this standard, however, there are a number of issues that we would like to see clarified before this standard is finalized.

Specific Comments:

DEFINITIONS AND ABBREVIATIONS

Comment: The words used to define “dosimetry “ are appropriate only for the term “dosimetry system.” Add the word “system” to the term being defined.

GUIDELINES

Comment: Page 6, Section 4, Dosimetry. Dose measurement (dosimetry) is the single most important parameter of the whole treatment process and must be carried out with precision and care with calibrated dosimeters which are known to be suitable for the particular application, dose range, etc. As a result, it is imperative that most of the “should” read “must” or “shall”. For example, in the second paragraph of Section 4, the dosimeters SHALL or MUST be appropriate for the treatment conditions. The alternative, using inappropriate dosimeters, would not be acceptable.

Comment: Page 6, Section 4, starting with the second sentence in the first paragraph. Change to read, “The selection of the dosimetry system shall be such that the dosimeter response range overlaps the entire range of doses likely to be received by the product. In addition, the dosimetry system shall be calibrated in accordance with international standards or appropriate national standards.”

Comment: Page 6, Section 4, end of the last paragraph add, International ISO Guidelines are available for selecting the most appropriate dosimetry systems for a given application (see reference).” And then add the reference, “Standard ISO/ASTM 51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing, International Organization for Standardization, 1 Rue de Varemba – (C), Case Postal 56, CH-1211, Geneva 20, Switzerland.”

Comment: Page 7, Section 5, Change to read, “Documented dose mapping should be done following repairs, modifications, or adjustments in equipment or processes that affect the absorbed dose.”

Comment: Page 9, Section 7.2, ninth dash mark, change to read, “absorbed doses – target and measured,” because there will never be a single measured dose, but only a dose range.”

ANNEX 2

Comment: Under “Research materials”, in the Note add the following to the end of the sentence, “unless preliminary testing indicates that results from in vitro treatments are no different than in situ.”

Comment: Under “Dosimetry”, add the following sentence, “International ISO Guidelines are available for conducting dosimetry in radiation research on food and agricultural products (see reference).” Add to reference section, “Guide for Dosimetry in Radiation Research on Food and Agriculture Products, International Organization for Standardization, 1 rue do VarembA-C©, Case Postale 56, CH-1211, Geneva 20, Switzerland.”

Comment: Under “Estimation and confirmation of minimum absorbed dose for treatment”, second bullet, second sentence, after “to use five (5) dose levels” add, “at a minimum”. Many researchers use up to 12 doses and 4-5 replications. With variable data more dose levels and more replicates are desirable. For determining the optimum treatment dose (often probit 9) the data is fitted to some model. If any of the five data points are zero mortality or 100 percent mortality, then fitting a model with only five points will not give enough data to allow determination of whether the model fit is adequate. With three points almost any statistical model can be fitted. So the five dose levels used should be chosen with care so that non-negative numbers are included. It is much better to include more dose levels (possibly with fewer insects per dose or replication) than thousands of insects at only a few doses.

Also, the number of organisms used depends to a great extent on how easy it is to get them. For example, getting hundreds of mango seed weevils is extremely difficult. To account for this add the phrase, “where possible” after “50 individuals”.

Comment: Under the third bullet, add the following, “Any study where the control or check mortalities are high indicates that the organisms were held and handled under suboptimal conditions. These organisms may give misleading results if their treatment mortality is used to predict an optimum treatment dose. A general rule of thumb is that mortality in the control or check should not exceed 10%.”

ANNEX 3

Comment: In Section 4, box 3 add, “using a calibrated dosimetry system”, at the end of the first sentence.

Comment: Under #3, add, “There is a physical separation between incoming and outgoing holding areas.” It is extremely easy to accidentally move untreated fruit into the wrong area and have it shipped without treatment. Treated fruit might also accidentally receive multiple treatments, exceeding regulatory agency guidelines for allowed amount of treatment for a commodity that is to be consumed.